

HN (NI) 2002/06

DATE: 29 August 2002

**For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency**



**HEALTH ESTATES
ESTATE POLICY**

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

TITLE:

**AQUARIUS HAEMOFILTRATION MACHINE –
SPLITTING OF AQUALINE TUBING SETS**

MANUFACTURER/SUPPLIER

Edwards Lifesciences

PROBLEM

NIAIC has been informed that Medical Devices Agency (MDA) has received several reports of Aqualine tubing for the Aquarius haemofiltration machine splitting at the blood pump segment, and at the filtrate, substitution and predilution pump segments. There have been no patient injuries reported with these events. Edwards Lifesciences has identified the root cause of the blood pump segment splitting to be a sharp edge in the blood pump housing. The root cause of the splitting of the filtrate, substitution, and predilution pump segments was found to be incorrect insertion of these segments into the pump housing or dislocation of the segments during use. Edwards Lifesciences will be implementing a Field Corrective Action to rectify these problems within the first week of September 2002.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Device Managers
- Estates Managers
- Medical Directors
- Renal Technicians
- Renal Physicians
- Intensive Care
- Nurse Directors
- Dialysis Units

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

IMMEDIATE ACTION

- Until the manufacturer has fixed an inlay into the blood pump housing and fitted pump door elements to all the Aquarius's pumps, users should use alternative haemofiltration machines where possible.
- Where there is no alternative and treatment is essential, users can continue to use the Aquarius. However, they should ensure that the tubing is correctly loaded in the blood pump section and follow the instructions issued by the manufacturer in the customer letter dated 5 July 2002 and exercise additional vigilance.
- The patient should be monitored frequently and the blood pump regularly checked to ensure that the tubing has not become displaced.
- Users should ensure that precautions are taken against cross contamination of blood spillages, should the tubing split.

**HAZARD
NOTICE**

- Edwards Lifesciences will start the Field Corrective Action on 2 September 2002, and complete modifications to all Aquarius machines by 6 September 2002.
- NIAIC will issue further advice once updated information has been received from the manufacturer. Edwards Lifesciences will provide details of additional training on proper loading.

BACKGROUND

NIAIC has been informed that the MDA has received several reports of Aqualine tubing for the Aquarius haemofiltration machine splitting at the blood pump segment. The root cause of this problem has been identified to be a sharp edge in the blood pump housing. Additional vigilance is required by users as there have been reports of the blood pump segment splitting and the alarms not activating at low flow rates. Splitting of the filtrate, substitution and predilution segments is caused by incorrect loading of these segments into the pump housing or dislocation during use. If the pump segment of the line is not perfectly loaded, it may be pinched between the rotor and the stator of the pump. This pinching of the line may cause material abrasion, which could lead to splitting of the tubing.

Although there have been no reports of patient injury associated with these incidents, Edwards Lifesciences issued a customer letter dated 5 July 2002, with additional instructions on how to load the tubing correctly. Edwards Lifesciences will be implementing a Field Corrective Action on 2 September 2002. This will involve inserting an inlay to cover the sharp edge in the blood pump segment and fitting pump door elements to all pump doors to prevent improper insertion of the tubing into the pump segments and prevent dislocation of the tubing during use.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Kieron O'Neil
UK Haemofiltration Product Specialist
Edwards Lifesciences Ltd
2 Tooners Wharf
Canal Walk
Newbury
Berkshire
RG14 1DY

Tel: 07770 443 929 or 0870 606 2040
Fax: 0870 606 2050
Pager: 07693 205 758

Enquires to the NIAIC should quote the reference number HN(NI) 2002/06 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC), Health Estates, Estate Policy
Directorate, Stoney Road, Dundonald, Belfast BT16 1US
Tel: 02890 523714, Fax: 02890 523900, Email: brian.godfrey@dhsspsni.gov.uk

Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2002/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety
Áisíneacht Feidhmeannach don Roinn Sláinte, Serbhísí Sóisialta agus Sábháilteacht Phoiblí*

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**HAZARD
NOTICE**